

## REMARKS

It is respectfully submitted that the present response presents no new matter. Reconsideration of the application in view of the following remarks is requested. Entry of this response is appropriate because it places the case in better condition for appeal.

### I: The IDS

The Examiner indicated that the IDS submitted on 02/21/2008 has been acknowledged. However, the Examiner indicated that "a copy of said foreign documents have not been provided by applicants".

Applicants filed an IDS on 23 Jan 2009. The references and related English language documents are available in PAIR. Consideration is urged.

### II: The Rejection of Claims 1-12, 14-20, 44, 47-49, 52-56 under 35 U.S.C. 103(a)

The Examiner rejected claims 1-12, 14-20, 44, 47-49 and 52-56 as obvious in light of U.S. patent No. 6,268,222 (herein after referred to simply as "Chandler").

Obviousness is a question of law based on underlying findings of fact. An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any. See Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). The teachings of a prior art reference are underlying factual questions in the obviousness inquiry. See Para-Ordnance Mfg., Inc. v. SGS Imp. Int'l, Inc., 73 F.3d 1085, 1088 (Fed. Cir. 1995).

As previously explained, dust formation and instability issues are problematic in the enzyme industry. Enzyme producers granulate to minimize these problems. However, the amount of enzyme that can escape from a granulated product, e.g. in the form of dust, must also be minimized to ensure that persons handling the product do not suffer any adverse effects from enzyme contact. Further, enzyme must be protected from the environment to remain stable and active until the time of intended use.

Applicants created a novel process for analyzing granular composition(s) to determine one or more quality parameters of granule(s). The novel process solves problems in granule formulation and/or reduces risks associated with active dust. The fluorescent analysis of the present disclosure is useful for, *inter alia*, determining one or

more quality parameters of enzyme granules. For example, the process in accordance with the present disclosure can be used to predict the thickness of the coating on an enzyme granule, or estimate the amount of biologically active dust in granular compositions. Applicants novel process is a contribution to the art as demonstrated in the examples. The level of skill is high.

Chandler *et al.* does not relate to enzyme granules and instead relates to a fluorescent article including a core or carrier particle having on its surface a plurality of smaller polymeric particles or nanoparticles, which are stained with different fluorescent dyes. When excited by a light source, the Chandler particles are capable of giving off multiple fluorescent emissions simultaneously, which is useful for multiplexed analysis of a plurality of analytes in a sample. The fluorescent articles of Chandler can be used for, *inter alia*, passive and covalent coupling of biological material, *i.e.*, analyte or analytical reactants and used for various types of assays.

Independent claims 1, 44, 49 and 54 require, *inter alia*, a layer around the granule that absorbs light from the fluorescent marker. Since the present disclosure is concerned with quality parameters of the enzyme granules, it is possible to add a layer which affects the absorption of light entering and/or emitted from a granule. See for example, page 25, lines 23-27. Conversely, the articles of Chandler are not enzyme granules, thus are different than enzyme granules in accordance with the present disclosure and not interested in solving the problems associated with enzyme granules. The differences are such that Chandler is capable of teaching away from using a layer which would affect the absorption of light -- a limitation required by every independent claim of the present disclosure. See, column 12, lines 15-18 of Chandler which states:

The article can be further coated or surrounded by a thin polymeric shell, selected in such a way that it would not affect light absorption and emission characteristics.

As Chandler teaches away from a light absorbing layer of the present disclosure, one of skill in the art would not substitute the polymeric shells of Chandler for the layers of the present disclosure. Accordingly, claims 1, 44, 49 and 54 are not obvious.

The Examiner maintains that Chandler reads on the first and second granular composition of Claim 1. Applicants respectfully disagree, and note that this mere conclusory statement is deficient in satisfying the requirements for a *prima facie* case of obviousness. No appropriate rationale for obviousness has been offered by the Examiner. Initially, Applicants note that the Examiner's position is inconsistent with the Examiner's position that "Chandler does not expressly teach the specific layered structure of particles as instantly claimed." Applicants respectfully submit that Chandler does not expressly or otherwise teach the specific layered structure of particles as claimed. Chandler is deficient and does not relate to enzyme granules in accordance with the present disclosure. One of skill in the art would understand that the present disclosure relates to granules and not the articles of Chandler and that the Examiner is incorrect in maintaining that Chandler reads on the first and second granular composition of Claim 1. Since Chandler relates to other articles (not enzyme granules), Chandler does not require the use of a layer around the article that absorbs light from the fluorescent marker. Claims 1, 44, 49, and 54 clearly require a layer around the second granule that absorbs light from the fluorescent marker. Accordingly, Chandler does not read on any independent claim and does not make the claimed invention obvious.

Thus, Chandler fails to show each and every element of the present disclosure, and Chandler fails to make claims 1, 44, 49, and 54 and all claims that depend therefrom obvious. The Examiner has erroneously retraced the path of the inventor with hindsight – discounting the number of complexities of the alternatives in order to conclude that the specifically claimed method was obvious. This reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

A patent claim is obvious over . . . prior art references only when "the prior art would have suggested to one of ordinary skill in the art that [the claimed invention] should be carried out and would have a reasonable likelihood of success. . . . Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical*, 837 F.2d 469, 473 (Fed. Cir. 1988); see also, 35 U.S.C. § 103. An invitation to experiment, alone, cannot make an invention obvious. *In re Dow*, 837 F.2d at 473.

Applicants believe there is no evidence given by Chandler that including a layer around the second granule that absorbs light from the fluorescent marker would be

suitable for enzyme granule analysis. A skilled person in the art would have no reasonable expectation of success that such a layer could be used to solve the problems of the present disclosure. For example, the references do not suggest that the claimed steps could be used to predict the thickness of the coating on an enzyme granule, or estimate the amount of biologically active dust in granular compositions. Even if it was obvious to try to experiment it is not necessarily true that there would be any reasonable expectation of success. Applicants' examples show that the Applicants have made a contribution to the art.

Even applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by Chandler to modify the fluorescent articles of Chandler to include a layer around the granule that absorbs light from the fluorescent marker as required by claims 1, 44, 49 and 54. This is especially true where column 12, lines 15-18 of Chandler teaches away from the concepts of the present disclosure by teaching how to not affect light absorption and emission characteristics.

For these reasons, claim 1, 44, 49, and 54 and all claims which depend therefrom are not obvious by Chandler and should not be rejected under 35 U.S.C. 103(a).

### III. Conclusion

While it is believed that all fees relating to this response were paid electronically at the time of filing this response, the USPTO is authorized to charge any additional fees to Novozymes North America, Inc.'s deposit account number 50-1701 should any additional fees be required.

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: May 11, 2009

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